#24

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On April 15, 2004

TOWNSEND and TOWNSEND and CREW LLP

By: Gigi Hoover

PATENT
Attorney Docket No.: 017516-007400US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

PHILIP S. GREEN

Patent No.: 5,808,665

Issued: September 15, 1998

For: ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD OF USE

Customer No.: 20350

PETITION TO DIRECTOR FOR QUESTIONS NOT SPECIFICALLY PROVIDED FOR UNDER 37 C.F.R. § 1.182

Mail Stop Petition
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.182, Applicants are filing this petition for questions not specifically provided for in the regulations to invoke the supervisory authority of the Director. Please deduct the requisite fee, pursuant to 37 C.F.R. § 1.17(h), of $130 from deposit account 20-1430, and deduct any additional fees or credit any excess fees associated with this petition to such deposit account.

04/21/2004 AWONDAF2 00000070 201430 08709965
01 FC:1460 130.00 DA

STATEMENT OF FACTS

A patent term extension application of U.S. Patent No. 5,808,665 was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration ("FDA") approval of the da Vinci® Robotic Surgery System. A Final Determination of Ineligibility was mailed from the U.S. Patent and Trademark Office ("USPTO") on November 14, 2001. A timely request for reconsideration of the final determination of the patent term extension of the '665 patent was filed on January 9, 2002, a copy of which is attached hereto as Exhibit A. In April of 2002, Applicants were copied[1] on a letter by Karin Ferriter, Senior Legal Advisor for the Office of Patent Legal Administration and Office of the Deputy Commissioner for Patent Examination Policy of the USPTO, to David T. Read, Acting Director Health Assessment Policy Staff, CDER of the FDA. This letter, a copy of which is attached hereto as Exhibit B, forwards Applicants request for reconsideration to the FDA for comment in order to assist the USPTO to reconsider the final determination of ineligibility.

To date, Applicants have not received any further official correspondence from the USPTO or FDA regarding our request for reconsideration.

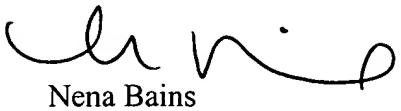
ACTION REQUESTED

Applicants filed the reconsideration request over two years ago with the USPTO and to date have not received any determination regarding this request which was filed on January 9, 2002. As such, Applicants request that the Director invoke supervisory authority over the Offices of Patent Legal Administration and/or the Deputy Commissioner for Patent

[1] Sally Yeager of Alcon Laboratories Inc. was copied in error.

Examination Policy of the USPTO to move this reconsideration request forward and to advise us of the status of this request.

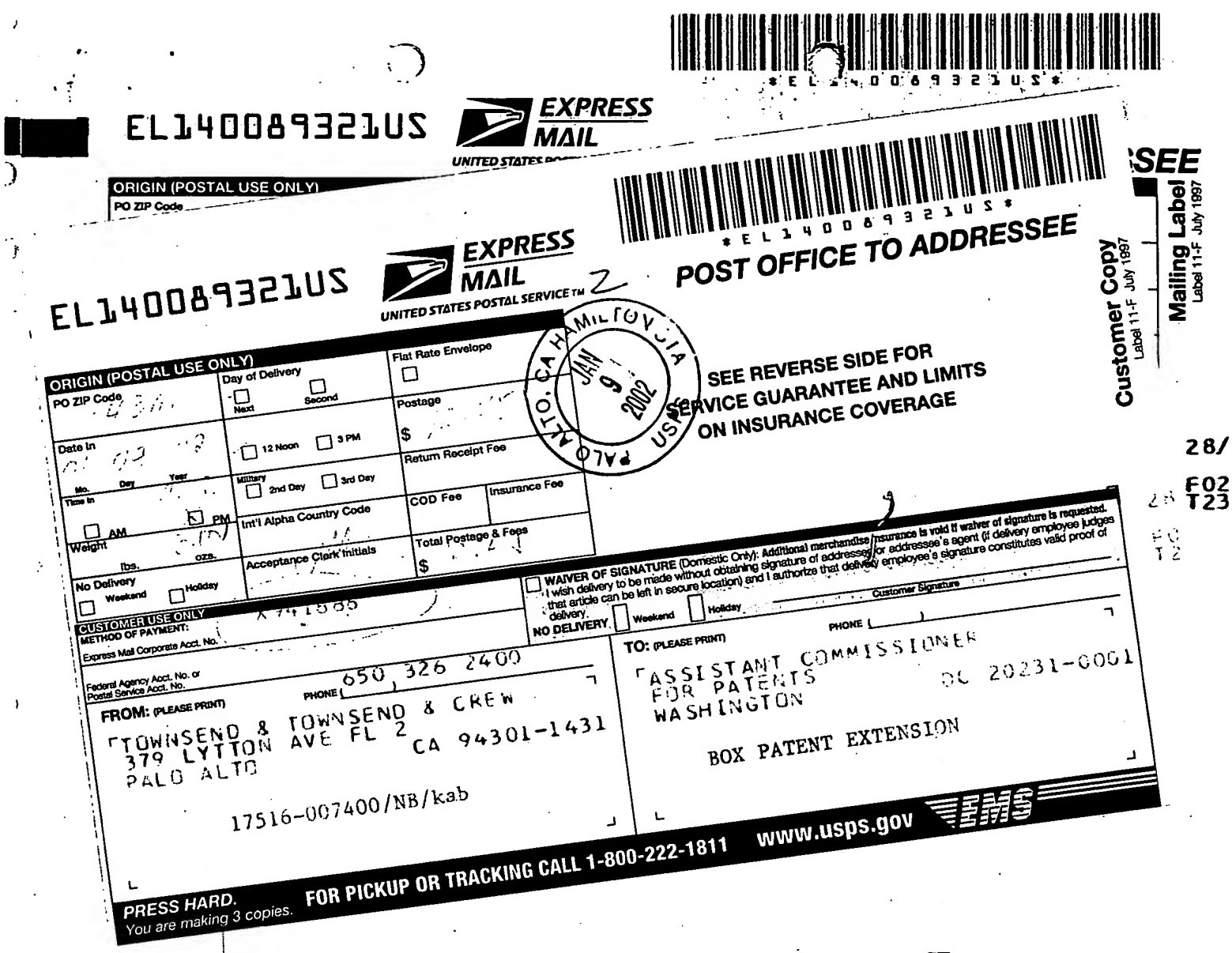
Respectfully submitted,



Nena Bains
Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments: Exhibit A
Exhibit B

NB
60192571 v1



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F02
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION
Filing Acknowledgment

Mailing Date:	Jan
File No.:	175
Applicant:	GR
Title:	En

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- ✓ Request for F
- ✓ Return Postc

DUE DATE: Ja

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION
Filing Acknowledgment

Mailing Date:	January 9, 2002	Serial No.	08/709,965
File No.:	**17516-007400**	Attorney:	MDB/NB/**kab**
Applicant:	GREEN, Phillip S.		
Title:	Endoscopic Surgical Instrument and Method of Use		

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- ✓ Transmittal Form
- ✓ Fee Transmittal
- ✓ Petition For Extension of Time
- ✓ Request for Reconsideration for Patent Term Extension
- ✓ Return Postcard

DUE DATE: January 14, 2002 Express Mail Label No. EL140089321US

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FROM: (PLEASE PRINT) PHONE 650 326 2400
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379 LYTTON AVE FL 2
PALO ALTO CA 94301-1431
17516-007400/NB/kab

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T2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION

Filing Acknowledgment

Mailing Date:	January 9, 2002	Serial No.	08/709,965
File No.:	17516-007400	Attorney:	MDB/NB/kab
Applicant:	GREEN, Phillip S.		
Title:	Endoscopic Surgical Instrument and Method of Use		

Please stamp the date of receipt of the enclosed documents and return this card to addressee

- ✓ Transmittal Form
- ✓ Fee Transmittal
- ✓ Petition For Extension of Time
- ✓ Request for Reconsideration For Patent Term Extension
- ✓ Return Postcard

U.S. PATENT AND TRADEMARK OFFICE JAN 09 2002 C32

EL140089321US

DUE DATE: January 14, 2002 Express Mail Label No. EL140089321US

Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/709,965
Filing Date	September 9, 1996
First Named Inventor	GREEN, Phillip S.
Group Art Unit	
Examiner Name	
Total Number of Pages in This Submission: 7	
Attorney Docket Number	017516-007400US

ENCLOSURES *(check all that apply)*

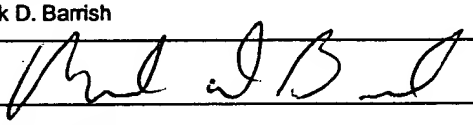
- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Response
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s)
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below)*:

Request for Reconsideration for Patent Term Extension under 35 U.S.C §156 and Return Postcard

Remarks

The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Mark D. Barrish Reg. No. 36,443
Signature	
Date	January 9, 2002

CERTIFICATE OF MAILING

Express Mail Label: EL140089321US

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Assistant Commissioner for Patents, Washington, D.C. 20231

Typed or printed name	Daniel Miranda		
Signature		Date	January 9, 2002

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be send to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PA 3194291 v1

PTO/SB/17 (09-00)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

Complete If Known	
Application Number	08/709,965
Filing Date	September 9, 1996
First Named Inventor	GREEN, Philip S.
Examiner Name	
Group Art Unit	
Attorney Docket No.	017516-007400US

TOTAL AMOUNT OF PAYMENT ($) 55

METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 20-1430

Deposit Account Name: Townsend and Townsend and Crew LLP

☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☒ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ Payment Enclosed:

☐ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES

			Extra Claims		Fee from below	=	Fee Paid
Total Claims		-20**	=	X		=	
Independent Claims		-3**	=	X		=	
Multiple Dependent				X		=	

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	55
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive – unavoidable	
141	1,280	241	640	Petition to revive – unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	
179	740	279	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	
Other fee (specify)					

The Commissioner is authorized to charge any additional fees to the above noted Deposit Account.

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)55

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Mark D. Barrish	Registration No. (Attorney/Agent)	36,443	Telephone	650-326-2400
Signature				Date	January 9, 2002

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 PA 3194287 v1

PTO/SB/22 (10-00)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Docket Number (Optional) 017516-007400US

In re Application of PHILLIP S. GREEN	
Application Number 08/709,965	Filed September 9, 1996
For ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD OF USE	
Group Art Unit	Examiner

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

☒	One month (37 CFR 1.17(a)(1))	$110
☐	Two months (37 CFR 1.17(a)(2))	$
☐	Three months (37 CFR 1.17(a)(3))	$
☐	Four months (37 CFR 1.17(a)(4))	$
☐	Five months (37 CFR 1.17(a)(5))	$

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: $ 55 .

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 20-1430.

I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record.

☐ attorney or agent under 37 CFR 1.34(a).

Registration number if acting under 37 CFR 1.34(a). _____ .

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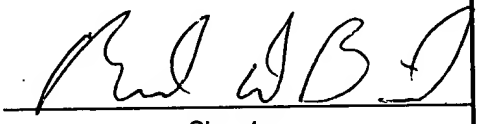
January 9, 2002
Date


Signature

Mark D. Barrish, Reg. No. 36,443
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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BOX PATENT EXTENSION
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Washington, D.C. 20231

By: Daniel Miranda

PATENT

TTC Docket No. 017516-007400US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Phillip S. Green

Patent No.: 5,808,665

Issued: September 15, 1998

Title: ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD FOR USE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Hon. Commissioner of Patents and Trademarks
Box: Patent Extension
Washington, D.C. 20231

Sir:

Applicants respectfully request reconsideration for a patent term extension of U.S. Patent No. 5,808,665. A patent term extension request was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration (hereinafter "FDA") approval of the da Vinci™ Robotic Surgery System. A Final Determination of Ineligibility (hereinafter "Determination") was mailed from the Patent Office on November 14, 2001.

Dismissal of the application for the subject patent term extension was apparently based on the determination by the Commissioner of Patents and Trademarks (hereinafter "Commissioner") that the da Vinci™ System underwent regulatory review under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA"). Determination, page 2. However, as properly determined by the FDA, the da Vinci™ system was subjected to a regulatory review period as defined by 35 U.S.C. §156(a)(4), including regulatory review under section 515 of the FFDCA. FDA letter dated October 2, 2001.

The regulatory review of the da Vinci™ System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k). As the da Vinci™ System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension. Per 35 U.S.C. §156(d)(2), the Secretary of Health and Human Services is responsible for determining the Regulatory Review Period for medical devices, and this matter was properly referred to the FDA. In a preliminary eligibility decision, the FDA informed the Commissioner that a "review of the Food and Drug Administration's official records indicates that this product **was subject to a regulatory review** period before its commercial marketing or use, **as required under 35 U.S.C. § 156(a)(4).**" *Id* (Emphasis added).

Reviewing the language of the statute, 35 U.S.C. § 156(a)(4), requires that, "the product has been subject to a regulatory review period before its commercial marketing or use." For medical devices, the term "regulatory review period" is defined in § 156(g)(3)(B) as follows:

> (i) the period beginning on the date a clinical investigation on human involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and **ending on the date such application was approved under such Act** or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added). Therefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the "Act," i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5.

The FDA correctly verified that Applicants meet the statutory requirements for a regulatory review period under the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B). *Id.* Specifically, Applicants began their first clinical investigations on humans on July 27, 1998. On January 17, 1999 Applicants submitted a section 510(k) application

#K990144 to the FDA seeking laparoscopic approval for its da Vinci™ System. On May 19, 1999, the FDA reclassified the da Vinci™ System into a class III device requiring Pre-Market Approval (hereinafter "PMA") under section 515. Applicants complied with the FDA mandated reclassification by (a) submitting a complete PMA application #P990079 on November 18, 1999 based on the same clinical data gathered during its earlier human clinical investigations, and (b) requesting that the FDA approve the da Vinci™ System under section 515 for laparoscopic procedures. The FDA accepted the PMA application for filing on November 29, 1999. On May 22, 2000, the FDA again reclassified the da Vinci™ System so that its corresponding PMA application #P990079, which had been reviewed for over a year under section 515, was reverted back to a 510(k). On July 11, 2000, the FDA approved the 510(k) application #K990144, with the submission date marked as November 18, 1999, the date the PMA application #P990079 under section 515 was submitted to the FDA.

As a final matter, Applicants gratefully acknowledge the Patent Office's correct determination that the Patent Term Extension request was timely filed. Determination, page 1. The FDA communication raised the issue as to whether the application was timely filed within the sixty-day (60) statutory period under 35 U.S.C. § 156(d)(1). FDA letter dated October 2, 2001. While the FDA often possesses information which is not readily available to the Commissioner, the Commissioner has primary responsibility for the eligibility determination. See M.P.E.P. § 2756. The Commissioner correctly determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms. Determination, page 1. The date of product approval was July 11, 2000. The present patent term extension application was filed on Monday, September 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. § 21(b) states that

> When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

As Monday, September 11, 2000 was the next succeeding business day following the last day (Saturday, September 9, 2000), the application was timely filed.

As the FDA has verified that the present application satisfies the statutory

requirements for a regulatory review period under 35 U.S.C. § 156(a)(4) and the Commissioner has determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms, the last day of said sixty-day (60) period being September 11, 2000, the present application qualifies for a patent term extension. For the foregoing reasons, reconsideration and granting of Applicants application for patent term extension is respectfully requested.

Respectfully submitted,

1/8/02

David M. Shaw
Reg. No. 38,688
Chief Patent Counsel
Intuitive Surgical, Inc.
Tel: (650) 237-7000
Fax: (650) 526-2060

PA 3191866 v1

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

APR 9 2002

RECEIVED

APR 15 2002

SSY

Dear Mr. Read:

A determination was made that U.S. Patent No. 5,808,665, which claims the medical device da VINCI™ System, is ineligible for patent term extension under 35 U.S.C. §156 because the medical device da VINCI™ system underwent regulatory review under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA), not under section 515 of the FFDCA and, as a result, was not eligible for patent term extension. See Manual of Patent Examining Procedure, Section 2751, page 2700-14, Eighth edition (August 2001), citing In re Nitinol Medical Tecimologies Inc., 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). See also Baxter Diagnostics v. AVL Scientific Corp., 798 F. Supp. 612, 619-620; 25 USPQ2d 1428, 1434 (1992)(Congress intended only Class III medical devices to be eligible for patent term extension).

In reply, on January 9, 2002, applicant explained that the regulatory review period of the product was as required by 35 U.S.C. 156(g)(3)(B), because regulatory review was conducted under Section 515 of the FFDCA, and the subsequent approval under the Act, albeit under section 510(k) of the Act, did not diminish the patent's eligibility for patent term extension. Applicant relies upon the Food and Drug Administration's prior conclusion that applicant met the statutory requirements for regulatory review in support of their argument that the patent is eligible for extension.

FDA is requested to comment upon the reply (a copy of which is enclosed) in order to assist the U.S. Patent and Trademark Office reconsider the final determination of ineligibility.

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159. E-mail inquiries should be directed to Karin.Tyson@uspto.gov.

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Sally Yeager
Alcon Laboratories Inc.
R&D Counsel Q-148
6201 South Freeway
Forth Worth TX 76134

US005808665A

United States Patent [19]

Green

[11] Patent Number: 5,808,665

[45] Date of Patent: Sep. 15, 1998

[54] ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD FOR USE

[75] Inventor: Philip S. Green, Redwood City, Calif.

[73] Assignee: SRI International, Menlo Park, Calif.

[21] Appl. No.: 709,965

[22] Filed: Sep. 9, 1996

Related U.S. Application Data

[63] Continuation of Ser. No. 823,932, Jan. 21, 1992, abandoned.

[51] Int. Cl.[6] H04N 7/18

[52] U.S. Cl. 348/65; 600/101

[58] Field of Search 348/61, 65, 143, 348/159, 207; 600/101, 109; 901/1, 2, 9, 30, 33, 34, 36; H04N 7/18

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(List continued on next page.)

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WO 92/16141 10/1992 WIPO .

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(List continued on next page.)

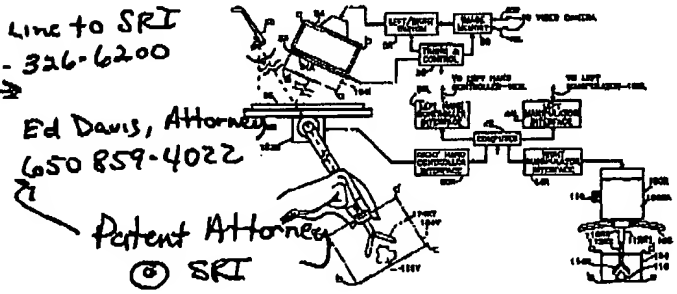
Primary Examiner—Richard Lee

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] ABSTRACT

A teleoperator system with telepresence is shown which includes right and left hand controllers (72R and 72L) for control of right and left manipulators (24R and 24L) through use of a servomechanism that includes computer (42). The teleoperator system comprises a endoscope surgical instrument suited for endoscopic surgery. The surgical instrument comprises a control servomechanism which operates an insertion section. The insertion section comprises a forearm, a wrist and an end effector. The end effector is a modified surgical instrument such as retractors, electrosurgical cutters, electrosurgical coagulators, forceps, needle holders, scissors, blades and irrigators. The control section contains motors and linkages which operate the insertion section with five or more degrees of freedom. The control section inserts, retracts, pivots and rotates the forearm with four degrees of freedom about axes that all intersect adjacent a small incision through which the insertion section is introduced to the patient. The control section also pivots the wrist with at least one degree of freedom relative to the forearm and operates the end effector. The surgical manipulator provides superior flexibility in performing endoscopic procedures compared to standard rigid endoscopic instruments and is adapted for teleoperator control.

32 Claims, 9 Drawing Sheets



Direct Line to SRI
650-326-6200

Ed Davis, Attorney
650 859-4022

Patent Attorney

© SRI

Alcon
RESEARCH, Ltd.

6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 293-0450

(817) 551-4031 - TELEPHONE
(817) 551-4610 - TELEFAX

April 23, 2002 INTELLECTUAL PROPERTY LAW AND R&D COUNSEL

-TELEFAX TRANSMISSION COVER SHEET-	
TO:	Ed Davis
NUMBER:	650-859-6420
FROM:	Sally Yeager
RE: U.S. Patent No. 5,808,665	
MESSAGE: Mr. Davis, Per our conversation, here is a fax of the letter I was copied on from the U.S.P.T.O. I believe I was copied on error. Sally Yeager Assistant General Counsel, Alcon Research, Ltd.	
THIS FAX CONSISTS OF 1 PAGE INCLUDING THIS COVER SHEET.	
NOTE: If you do not receive all pages, please call Sue Stockton at (817) 551-8819 as soon as possible. THANK YOU!	

Intellectual Property Office
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

Facsimile Transmittal Sheet

To:
FAX Number: 408-523-1390
Attention: Robert Dennis
Company: Intuitive Surgical
Date: 4/24/02
From: Edward E. Davis
Direct phone: (650)-859-4022

Return messages to FAX number (650)-859-6420. Number of pages: 4 including this page.

Re: US Patent 5,808,665
Request for Term Extension —

Bob—

Sally Yeager at Alcon Labs received this ("in error") & forwarded it to me.

Ed

DAC/#

PTO/SB/21 (08-03)

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/709,965
Patent Number	5,808,665
Issue Date	September 15, 1998
First Named Inventor	GREEN, PHILIP S.
Art Unit	
Examiner Name	
Attorney Docket Number	017516-007400US

Total Number of Pages in This Submission

ENCLOSURES ***(Check all that apply)***

- ☒ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☒ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:

  Exhibits A and B; Return Postcard

Remarks

The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Townsend and Townsend and Crew LLP Nena Bains Reg. No. 47,400
Signature	
Date	4/15/04

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Gigi Hoover		
Signature	Gigi Hoover	Date	April 15, 2004

PTO/SB/17 (10-03)

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT | ($) 130

Complete if Known	
Application Number	08/709,965
Patent Number	5,808,665
Issue Date	September 15, 1998
First Named Inventor	GREEN, PHILIP S.
Examiner Name	
Art Unit	
Attorney Docket No.	017516-007400US

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 20-1430

Deposit Account Name: Townsend and Townsend and Crew LLP

The Director is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below	Fee Paid
Total Claims		-** =		X		=
Independent Claims		-** =		X		=
Multiple Dependent				X		=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) ----------

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($)130

SUBMITTED BY					Complete *(if applicable)*
Name (Print/Type)	Nena Bains	*Registration No. (Attorney/Agent)*	47,400	*Telephone*	415-576-0200
Signature				*Date*	4/15/04

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60195006 v1

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BOX PATENT EXTENSION
Commissioner for Patents
Washington, D.C. 20231

By: Daniel Miranda

PATENT

TTC Docket No. 017516-007400US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Phillip S. Green

Patent No.: 5,808,665

Issued: September 15, 1998

Title: ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD FOR USE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Hon. Commissioner of Patents and Trademarks
Box: Patent Extension
Washington, D.C. 20231

Sir:

Applicants respectfully request reconsideration for a patent term extension of U.S. Patent No. 5,808,665. A patent term extension request was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration (hereinafter "FDA") approval of the da Vinci™ Robotic Surgery System. A Final Determination of Ineligibility (hereinafter "Determination") was mailed from the Patent Office on November 14, 2001.

Dismissal of the application for the subject patent term extension was apparently based on the determination by the Commissioner of Patents and Trademarks (hereinafter "Commissioner") that the da Vinci™ System underwent regulatory review under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA"). Determination, page 2. However, as properly determined by the FDA, the da Vinci™ system was subjected to a regulatory review period as defined by 35 U.S.C. §156(a)(4), including regulatory review under section 515 of the FFDCA. FDA letter dated October 2, 2001.

The regulatory review of the da Vinci™ System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k). As the da Vinci™ System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension. Per 35 U.S.C. §156(d)(2), the Secretary of Health and Human Services is responsible for determining the Regulatory Review Period for medical devices, and this matter was properly referred to the FDA. In a preliminary eligibility decision, the FDA informed the Commissioner that a "review of the Food and Drug Administration's official records indicates that this product **was subject to a regulatory review** period before its commercial marketing or use, **as required under 35 U.S.C. § 156(a)(4).**" *Id* (Emphasis added).

Reviewing the language of the statute, 35 U.S.C. § 156(a)(4), requires that, "the product has been subject to a regulatory review period before its commercial marketing or use." For medical devices, the term "regulatory review period" is defined in § 156(g)(3)(B) as follows:

> (i) the period beginning on the date a clinical investigation on human involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and **ending on the date such application was approved under such Act** or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added). Therefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the "Act," i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5.

The FDA correctly verified that Applicants meet the statutory requirements for a regulatory review period under the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B). *Id.* Specifically, Applicants began their first clinical investigations on humans on July 27, 1998. On January 17, 1999 Applicants submitted a section 510(k) application

#K990144 to the FDA seeking laparoscopic approval for its da Vinci™ System. On May 19, 1999, the FDA reclassified the da Vinci™ System into a class III device requiring Pre-Market Approval (hereinafter "PMA") under section 515. Applicants complied with the FDA mandated reclassification by (a) submitting a complete PMA application #P990079 on November 18, 1999 based on the same clinical data gathered during its earlier human clinical investigations, and (b) requesting that the FDA approve the da Vinci™ System under section 515 for laparoscopic procedures. The FDA accepted the PMA application for filing on November 29, 1999. On May 22, 2000, the FDA again reclassified the da Vinci™ System so that its corresponding PMA application #P990079, which had been reviewed for over a year under section 515, was reverted back to a 510(k). On July 11, 2000, the FDA approved the 510(k) application #K990144, with the submission date marked as November 18, 1999, the date the PMA application #P990079 under section 515 was submitted to the FDA.

As a final matter, Applicants gratefully acknowledge the Patent Office's correct determination that the Patent Term Extension request was timely filed. Determination, page 1. The FDA communication raised the issue as to whether the application was timely filed within the sixty-day (60) statutory period under 35 U.S.C. § 156(d)(1). FDA letter dated October 2, 2001. While the FDA often possesses information which is not readily available to the Commissioner, the Commissioner has primary responsibility for the eligibility determination. See M.P.E.P. § 2756. The Commissioner correctly determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms. Determination, page 1. The date of product approval was July 11, 2000. The present patent term extension application was filed on Monday, September 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. § 21(b) states that

> When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

As Monday, September 11, 2000 was the next succeeding business day following the last day (Saturday, September 9, 2000), the application was timely filed.

As the FDA has verified that the present application satisfies the statutory

requirements for a regulatory review period under 35 U.S.C. § 156(a)(4) and the Commissioner has determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms, the last day of said sixty-day (60) period being September 11, 2000, the present application qualifies for a patent term extension. For the foregoing reasons, reconsideration and granting of Applicants application for patent term extension is respectfully requested.

Respectfully submitted,

1/8/02

David M. Shaw
Reg. No. 38,688
Chief Patent Counsel
Intuitive Surgical, Inc.
Tel: (650) 237-7000
Fax: (650) 526-2060

PA 3191866 v1

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/709,965
Filing Date	September 9, 1996
First Named Inventor	GREEN, Phillip S.
Group Art Unit	
Examiner Name	
Total Number of Pages in This Submission: 7	
Attorney Docket Number	017516-007400US

ENCLOSURES *(check all that apply)*

- [X] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Response
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [X] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s)
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) *(please identify below)*:

Request for Reconsideration for Patent Term Extension under 35 U.S.C §156 and Return Postcard

Remarks

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Firm and Individual name	Townsend and Townsend and Crew LLP Mark D. Barrish Reg. No. 36,443
Signature	
Date	January 9, 2002

CERTIFICATE OF MAILING

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Typed or printed name	Daniel Miranda		
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PA 3194291 v1

PTO/SB/22 (10-00)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 017516-007400US

In re Application of PHILLIP S. GREEN

Application Number 08/709,965 | Filed September 9, 1996

For ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD OF USE

Group Art Unit | Examiner

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- ☒ One month (37 CFR 1.17(a)(1)) $110
- ☐ Two months (37 CFR 1.17(a)(2)) $
- ☐ Three months (37 CFR 1.17(a)(3)) $
- ☐ Four months (37 CFR 1.17(a)(4)) $
- ☐ Five months (37 CFR 1.17(a)(5)) $

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: $ 55 .

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 20-1430.

I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record.

☐ attorney or agent under 37 CFR 1.34(a).

Registration number if acting under 37 CFR 1.34(a). _____ .

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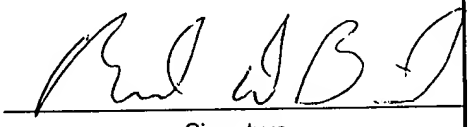
January 9. 2002
Date


Signature

Mark D. Barrish, Reg. No. 36,443
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

PA 3194286 v1

PTO/SB/17 (09-00)
Approved for use through 10/31/2002. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

	Complete if Known
Application Number	08/709,965
Filing Date	September 9, 1996
First Named Inventor	GREEN, Philip S.
Examiner Name	
Group Art Unit	
Attorney Docket No.	017516-007400US

TOTAL AMOUNT OF PAYMENT ($) 55

METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 20-1430

Deposit Account Name: Townsend and Townsend and Crew LLP

☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☒ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ **Payment Enclosed:**

☐ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Large Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES

			Extra Claims		Fee from below	=	Fee Paid
Total Claims		-20**		=		=	
Independent Claims		-3**		=		=	
Multiple Dependent						=	

Large Fee Code	Large Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	55
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive – unavoidable	
141	1,280	241	640	Petition to revive – unintentional	
142	1,280	242	640	Utility Issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	
179	740	279	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	
Other fee (specify)					

The Commissioner is authorized to charge any additional fees to the above noted Deposit Account.

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)55

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Mark D. Barrish	Registration No. (Attorney/Agent)	36,443	Telephone	650-326-2400
Signature				Date	January 9, 2002

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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